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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,965	01/22/2004	Xudong Huang	0492479-0033 (MGH 2231)	6347

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EXAMINER	
JONES, DAMERON LEVEST	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/762,965	HUANG, XUDONG	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/29/04; 3/9/05; 2/9/05; and 3/27/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *96-170* is/are pending in the application.

4a) Of the above claim(s) *96-122 and 143-170* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *123-142* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 June 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/29/04; 3/9/05; + 2/9/05*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 4/4/05 wherein claims 1-95 are canceled and claims 96-170.

Note: Claims 96-170 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed to compositions comprising at least one metal chelating moiety and at least one amyloid-binding moiety.

RESPONSE TO APPLICANT'S ELECTION

3. Applicant's election of Group VII (claims 123-142) in the reply filed on 3/27/06 is acknowledged. In addition, Applicant elected the species wherein the contrast imaging agent comprises gadolinium III (Gd3+) is complexed to the bifunctional molecule set forth in Figure 4A. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Thus, the restriction is deem proper and is made FINAL.

WITHDRAWN CLAIMS

4. Claims 96-122 and 143-170 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

DOUBLE PATENTING REJECTION

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 123-142 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7, 10-12, and 32 of copending Application No. 11/096,916. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compositions comprising at least one metal chelating moiety associated with at least one amyloid-binding moiety. The claims differ in that the claims of 11/096,916 disclose that the moiety comprises a derivatized benzothiazole and the metal chelating moiety comprises DTPA while the instant invention is not limited to any particular amyloid binding moiety and DTPA is listed as a component of the metal chelating moiety in one of the dependent claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

112 REJECTIONS

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 123-134 and 136-141 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 123-134 and 136-141: The claims as written are ambiguous because it is unclear what Applicant intends by the term 'imaging moiety associated with at least one

amyloid binding moiety'. In particular, is Applicant saying that the imaging/chelating moiety is ***conjugated*** to the amyloid-binding moiety or are the two moieties connected through a linking group, etc.? Please clarify in order that one may readily ascertain what is being claimed.

102 REJECTIONS

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 123-134 and 137-141 are rejected under 35 U.S.C. 102(e) as being anticipated by Gervais et al (US`2002/011717).

Gervais et al disclose amyloid targeting imaging agents and uses thereof. In particular, Gervais et al disclose amyloid targeting imaging agents such as radiolabeled amyloid targeting molecules and amyloid targeting molecule chelator conjugates for imaging amyloid plaques in vivo and/or for the treatment of amyloidosis disorders (see entire document, especially, abstract). The amyloid targeting imaging agents may be of Formula, At-(Alnk)z-Alab wherein At is an amyloid targeting moiety; Alnk is a linker moiety; and Alab is a labeling moiety (page 2, paragraph [0010]. The labeling moiety,

Alab, may be a metal chelate (a chelate of a metal with a ligand of Formula VII). In an advantageous embodiment, Alab includes a radionuclide. In cases where the amyloid targeting imaging agent includes a labeling moiety Alab (including a radionuclide) attached directly to amyloid targeting moiety At, and linker moiety Alnk is optional (page 3, paragraph [0035]). Labeling moieties Alab may include diagnostically or therapeutically useful radionuclides such as 3H, 129I, 125I, 131I, or 18Fe for use as radiopharmaceuticals. In one embodiment, the labeling moiety Alab includes Tc or Re. The labeling moiety Alab may also be a combination of radionuclide(s) and a metal chelator (page 3, paragraph [0036]). The labeling moiety may be an echogenic substance in the case of an ultrasound contrast agent; a paramagnetic metal chelate in the case of an MRI contrast agent; a radioactive atom (e.g., radioactive fluorine) or a chelated radioactive metal ion (e.g., In-111) in the case of a radionuclide imaging agent; a radio-opaque chelate or compound (e.g., a polyiodinated aromatic) for an x-ray contrast agent; or a fluorescent or colored dye in the case of an optical imaging contrast agent. In one embodiment labeling moiety Alab may be a metal chelator (page 14, paragraph [0156]). The selection of radionuclides include Tc-99m, Re-186, In-111, and Ga-67 (page 14, paragraph [0159]). In a particular embodiment, the labeling moiety, Alab, includes 129I, 125I, 131I, or 18F (page 15, paragraph [0161]). One aspect of Gervais et al involves an amyloid targeting molecule chelator conjugate of Formula VII (page 15). May chelators such as DTPA may be utilized (page 15, paragraph [0164]). The imaging compositions which target amyloid in vivo are capable of crossing the blood brain barrier to allow imaging (page 8, paragraphs [0092] – [0094]. Preferred)

include those that have specificity for Aβ amyloid deposits (page 8, paragraphs [0108] and [0109]; pages 9-10, SEQ ID Nos. 1-49). Pharmaceuticals comprising the compounds/compositions of the instant invention may be formulated with a variety of counter ions/carriers (page 12, page [0142]; page 16, paragraph [0172]). Contrast agents such as a peptide targeting moiety conjugated to DTPA is typically reacted with GdCl3 or Gd2O3 (page 17, paragraph [0177]).

Thus both Applicant and Gervais et al disclose a contrast imaging agent comprising at least one imaging/metal-chelating moiety associated with at least one amyloid binding moiety.

COMMENTS/NOTES

10. It should be noted that claims 135 and 142 are allowable over the prior art of record because the prior art neither anticipates nor renders obvious the imaging agent as set forth in independent claim 135. However, Applicant MUST address and overcome the double patenting rejection above.

SPECIFICATION

11. The disclosure is objected to because of the following informality. The specification is objected to because it does not contain the proper reference paragraph to the colored drawings. In particular, according to 37 C.F.R 1.84, standards for drawings, when colored drawings are present in the specification, an amendment to the specification to insert the following language as the first paragraph of the brief description of the drawings us necessary: 'The patent or application file contains at

least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request an payment of the necessary fee.'.

Appropriate correction is required.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Jones
Primary Examiner
Art Unit 1618

June 12, 2006